BROOKHAVEN NATIONAL LABORATORY
SELLERS' QUALITY ASSURANCE REQUIREMENTS
BNL-QA-101

PO/Contract No.: _____

INSTRUCTIONS: One subparagraph in section 3.1 must be selected which will automatically invoke paragraphs 3.2 through 3.8 collectively on purchase orders. If applicable, the Special Requirements of Section 4.0 need to be individually selected and can be modified as required.
(NOTE: Save this form to your desktop and select the appropriate clauses by clicking on the boxes ☐).

1.0 PURPOSE & SCOPE

1.1 This document establishes quality assurance requirements to which Sellers to Brookhaven National Laboratory (BNL) shall conform to when specified in the procurement documentation.

1.2 This document contains two main sections. Section 3.0 covers the general requirements that are applicable to all Sellers. Section 4.0 contains special quality requirements that are applicable only when specifically invoked in the procurement documentation.

2.0 DEFINITIONS

2.1 The term Procurement documentation means the purchase order (PO), contract, subcontract, Request for Proposal (RFP), Request for Quotation (RFQ) or other written agreement with the Seller (supplier) in which the requirements of BNL are incorporated.

2.2 The term Buyer means Brookhaven Science Associates (BSA) operating Brookhaven National Laboratory, acting by and through its Procurement & Property Management Division (PPM) issuing the purchase order / contract.

2.3 The term Seller means the legal entity, which is the contracting party, with the Buyer with respect to the procurement documentation.

2.4 The term article or item means a product and/or a service.

3.0 GENERAL REQUIREMENTS

Unless otherwise specified in the procurement documentation, the following General Requirements apply:

3.1 Seller's Quality System

The Seller shall have and maintain an effective quality system that will, as a minimum, comply with all of the requirements of the specification designated below:

☐ **3.1.1** A quality system certified/registered to the ISO 9001 standard: (Latest revision as of the date of issuing the procurement documentation).

☐ **3.1.2** A quality system that meets the requirements of the ISO 9001 standard: "Quality Management Systems – Requirements" (Latest revision as of the date of issuing the procurement documentation).

☐ **3.1.3** Conformance to Seller's/Manufacturer's system.

☐ **3.1.4** Other: Refer to requirements stated in the specification / procurement documentation.

NOTE: Paragraphs 3.2 through 3.7 apply to all purchase orders regardless of the quality system selected in 3.1 and will be included collectively in other procurement documentation when required / specified.

3.2 Assessment by Buyer

The Seller's Quality system is subject to assessments by the Buyer's Representative(s) for conformance with the requirements of the purchase order

3.3 Change Approval

No change(s) shall be made to any Buyer requirements without the prior written approval of the Buyer.

3.4 Responsibility for Subcontractors

It is the responsibility of the Seller to impose applicable quality assurance requirements upon their subcontractors. Additionally, the Buyer reserves the right to approve, in writing, any subcontractor**.**

3.5 Responsibility for Conformance

The Seller is responsible to provide items which conform to the requirements of the purchase order regardless of any assessments, surveillances, inspections and/or tests by the Buyer or its representatives at either the Seller's or Buyer's facility. The Buyer reserves the right to request failure analysis and corrective action for non-conforming articles or items submitted or supplied to the Buyer.

3.6 Protection of Material and Equipment

The Seller shall employ procedures, which assure adequate protection of material and equipment during shipment and while in storage. Such protection shall include special environmental packaging, as necessary. All items shipped (originally packaged or repackaged) to BNL or other locations cited in the purchase order or contract, shall comply with the requirements set forth in the National Motor Freight Traffic Associations' National Motor Freight definitions, specifications and basic requirements (e.g. size, strength and materials) for commonly used packages.

3.7 Measuring and Test Equipment (M&TE) Calibration

The Seller shall calibrate any M&TE used in the fulfillment of the purchase order requirements against certified standards that are traceable to national standards such as the National Institute of Standards and Technology (NIST). The Seller shall notify the Buyer of any condition found during the calibration, servicing or repair of measuring and test equipment that can affect the end item requirements.

4.0 SPECIAL REQUIREMENTS
The following Special Requirements are applicable only when specified in the procurement documentation or as indicated by check mark hereon. These Requirements can be modified as required.

INSTRUCTIONS: Since subparagraphs (e.g. 4.4.1) are tied to the main paragraph (e.g. 4.4), the requirements of the main paragraph will apply by default whenever any subparagraph is selected (regardless of whether the main paragraph was selected / checked).

☐ **4.1 Q.A. Program or Manual:** The Seller shall submit a copy of their Quality Assurance Program or Manual with their proposal for review and evaluation.

☐ **4.2 Configuration Control System:** The Seller shall establish and maintain a system to assure that all end items (including spares) are of the proper configuration, and that all approved configuration changes are incorporated at the specified effectivity points. Records shall be maintained verifying the configuration of each item.

☐ **4.3 Process Sheets, Travelers, etc.:** The Seller shall maintain a system of process sheets, shop travelers, or equivalent means to define the sequence of manufacturing, inspection, installation and test activities to be performed. Flow sheets, or equivalent, shall provide for sign-off by designated inspection personnel at specified inspection and test points, including, as required, re-inspection and re-test points, to assure completion as well as proper sequencing of required operations.

☐ **4.4 Manufacturing/Inspection/Test Plan:** Sixty (60) days prior to performance of work, the Seller shall submit for the Buyer's approval a Manufacturing / Inspection / Test Plan for the item(s) to be produced. Once approved, changes / revisions must be approved by the Buyer prior to implementation. The Plan shall satisfy one or more of the following as selected:

☐ **4.4.1** Identification of parts and subassemblies showing integrated flow into end item(s).

☐ **4.4.2** Identification of critical manufacturing operations, as well as inspection and test checkpoints.

☐ **4.4.3** The Plan may be a single document, or may make use of existing "travelers," or other suitable planning and control documents.

☐ **4.5 "Witness" Points:** The Buyer reserves the right to designate selected manufacturing, inspection, and/or test operations as "witness" points. The Seller shall provide the Buyer with five (5) working days notice in advance of reaching such witness points during the manufacturing and test cycle of each item.

☐ **4.6 Test and Inspection Procedures:** Test and inspection procedures required to demonstrate satisfactory completion of requirements shall be prepared by the Seller and submitted to the Buyer for approval sixty (60) days prior to use of such procedures. Once approved, changes / revisions must be approved by the Buyer prior to implementation.

☐ **4.7 Special Process:** Processes (e.g. welding, brazing, bonding, plating, chemical machining, chemical coating, chemical cleaning, precision cleaning, heat treating, or waste processing) that either cannot be verified non-destructively or require a unique (special) non-destructive test / inspection (e.g. radiographic inspection, ultrasonic testing, pressure leak testing) shall be performed in accordance with detailed written procedures. These procedures shall specifically describe the exact manner in which the processes are to be performed. Additionally, the following requirements apply as selected:

☐ **4.7.1** Copies of special process procedures shall be made available on request, for review by the Buyer's representative.

☐ **4.7.2** At least sixty (60) days prior to use on items deliverable to the Buyer, the Seller shall submit to the Buyer copies of all applicable process procedures for review and approval. Revisions or changes to Buyer-approved special process procedures must be submitted to the Buyer for review and approval prior to implementation.

☐ **4.7.3** Qualification of Procedures, Facilities, Equipment and Personnel - The Seller shall, prior to use, qualify the procedures / specifications, facilities, equipment and personnel that will be used for the performance of special processes. Only those personnel who have been qualified to perform a specific special process shall be used to perform that process. Records of such qualification shall be available to the Buyer's representative upon request.

4.8 Qualification of Procedures, Facilities, Equipment – superceded by 4.7.3

4.9 Qualification of Special Process Personnel – superceded by 4.7.3

☐ **4.10 End-Item Documentation Package:** The Seller shall provide a documentation package for each shipment of the item(s) supplied, which consists of objective evidence of compliance with purchase order requirements. This documentation package shall be complete, legible, indexed, and traceable to the item supplied, and shall contain the following, as applicable:

☐ **4.10.1** Copies of reports of all required or necessary inspections, examinations and tests, properly validated by the Seller's authorized personnel.

☐ **4.10.2** A listing of the as-built configuration of each delivered item; this may be defined by the use of drawing numbers and revisions, unique parts lists or other such means of positive identification.

☐ **4.10.3** Copies of nonconformance reports dispositioned as "rework / repair" or "use-as-is."

☐ **4.10.4** Copies of material test reports for specified materials, showing physical and chemical properties.

4.10.5 – superceded by 4.16

☐ **4.11 Release for Shipment:** The documentation package required in 4.10, shall be approved by the Buyer's representative prior to release of the item for shipment.

☐ **4.12 Shipment of Documentation Package to Buyer:** Three (3) copies of the documentation package required in 4.10 shall be shipped to the Buyer with or prior to each shipment of the purchased items.

☐ **4.13 Failure Reporting, Analysis and Corrective Action:** The Seller shall maintain a failure reporting, analysis and corrective action system which shall, as a minimum, evaluate, analyze and correct failures occurring during qualification, first article and end-item acceptance testing and inspection. The results of all failure evaluations and analyses shall be documented and available for review by the Buyer.

☐ **4.14 Source Inspection/Surveillance:** Items to be delivered require inspection, tests or surveillance by the Buyer's representative at the Seller's facility. Five (5) work days notice, for acceptance inspections and tests, shall be given by the Seller to the Buyer to permit scheduling of source inspection.

☐ **4.15 Chemical and Physical Test Report:** One copy of actual chemical and physical test report(s) for each heat, batch or lot shall accompany each shipment. Test reports shall list the actual parameters tested, the acceptable limits for each parameter, and shall contain the actual readings taken during test.

☐ **4.16 Certificate of Conformance (C of C):** With each shipment, per the procurement documentation, the Seller shall submit a certificate of conformance. In case of drop shipment, a copy of the certificate shall be submitted to the Buyer at the time of shipment. The certificate shall include the title of and be signed by an authorized representative of the company, and shall constitute a representation by the Seller that:

A. Materials used are those which have been specified by the Buyer, and that the items delivered were produced from materials for which the Seller has on file, reports of chemical or physical analysis, or any other equivalent evidence of conformance of such items to applicable specifications;

B. Processes used in the fabrication of items delivered were in compliance with applicable specifications forming a part of the purchase order/contract, or Buyer approved procedures or specifications;

C. The items as delivered comply with all applicable drawings, specifications and other requirements of the procurement documentation.

D. When specified, cleaning and cleanliness requirements have been completely satisfied. The C of C shall reference the Seller's applicable cleaning procedures.

4.17 Report with Each Shipment - superseded by paragraph 4.10.

☐ **4.18 First Article Acceptance:** Buyer acceptance of first article(s) is required prior to the production run. The first article(s) shall be identified as such, including the purchase order number / contract, part number, and part name. The Seller is required to:

☐ **4.18.1** Submit the first article(s) to the Buyer's representative for test/inspection to be conducted at the Seller's facility by the Buyer's representative.

☐ **4.18.2** Submit the first article(s) to the Buyer for test / inspection by the Buyer at the Buyer's facility.

☐ **4.18.3** Submit the first article(s) to the Buyer together with documents showing data representing results of the Seller's first article(s) test/inspection, including the actual dimension or value for each specified characteristic.

☐ **4.18.4** After Buyer acceptance of first article(s), all of the remaining units required by the purchase order/contract shall be produced by the Seller and the Seller's suppliers using the same design, materials, processes, methods and tooling that were used to manufacture the approved first article(s). Any changes must have prior approval from the Buyer.

☐ **4.19 Notification of Change to Design, Methods, or Processes:** The Seller shall immediately notify the Buyer of any significant changes (those that may affect form, fit, function, reliability, safety, or interchangeability) in product design, fabrication methods, material or processing from those used by the Seller at time of Seller's quotation or offer to the Buyer, which resulted in the purchase order.

☐ **4.20 Age/Shelf Life and Storage Control:** The Seller shall have an effective storage and age control system for items where acceptability is limited by the age or manner of storage of the item. The system must include a method of identifying the expiration date on the containers in which material is delivered to the Buyer. Special handling conditions shall be recorded on certifications and shipping documents covering the material delivered to the Buyer. At the time of receipt, the material shall not have less than three-quarters of its shelf life remaining, without prior written approval from the Buyer for each shipment.

☐ **4.21 Serial Numbers:** The Seller shall assign / mark a separate and distinct serial number to each end-item in accordance with the procurement documentation. A record of the serial number, for each part number, shall be maintained by the Seller.

☐ **4.22 Lot or Batch Numbers:** For items furnished in accordance with the procurement documentation, the manufacturing lot or batch number shall be indicated on the packing list, certifications and other applicable documents. Where impractical to mark individual parts due to size or shape, the lot or batch number shall be marked on identifying tags or the smallest unit package.

☐ **4.23 Material Traceability:** Materials used must be identified by material type, applicable specification and revision number, and be traceable to their lot number(s) and / or heat number(s). Traceability records shall be available for review by the Buyer's representative.

☐ **4.24 Shipment Destination Other than BNL:** The material ordered is to be shipped to other than the Buyer's facilities. Copies of the data required in accordance with the procurement documentation shall accompany the shipment; in addition, one copy of such data shall be mailed to the Buyer on the same day that shipment is made.
4.25 Heat Treat Bars - superseded by paragraph 4.7.

☐ **4.26 Burn-in:** Burn-in shall be performed on each completed item, per the procurement specification or Seller's Burn-In process approved by the Buyer. Records of burn-in testing, repairs and test results shall be maintained and shall be available to the Buyer's representative upon request.

4.27 Welding Procedures - superseded by paragraph 4.7

☐ **4.28 Weld/Braze Inspection Report:** A report(s) shall be submitted that indicates the complete inspection of welds or brazes from the initial fit-up stage through final inspection. Inspection reports shall be accompanied by all radiographic films, filler metal reports etc. The reports shall contain the signature or stamp, and title of an authorized Seller representative.

☐ **4.29 Radiographic Quality Requirements:** Items requiring radiographic inspection shall be radiographed and processed in accordance with the Seller's special process procedures that satisfy design specifications, standards or other procurement documentation requirements. Personnel reading and interpreting film shall have been examined and certified. Responsibility for this certification shall rest with the Seller, whether the Seller does the work or subcontracts to a specialized laboratory. A report of the findings shall include the name of the reader and the signature and title of a responsible representative. The radiographic film and a reproducible copy of the report shall accompany each shipment. An adequate method of identifying and cross-referencing each film exposure, report, and item shall be provided. When parts are serialized, serial numbers shall appear on the report and the film.

☐ **4.30 Nondestructive Test Reports:** All nondestructive testing shall be conducted in compliance with the Seller's special process procedures that satisfy the applicable provisions of the design specifications, or other procurement documentation requirements. Personnel and equipment utilized in performance of such tests shall be qualified for the type of test performed. The Seller shall furnish with, or prior to, each shipment reports of such nondestructive examination of material or items furnished. These reports shall be identifiable to the respective item or material including the specific section, joints or views of the item furnished. These reports shall contain the signature and title of an authorized Seller representative. When items are serialized, the serial numbers shall appear on the reports.

☐ **4.31 Pressure or Leak Test Reports:** Test reports shall be prepared for all pressure and leak tests. Such reports shall state the requirement, the Seller's test procedure number, and the observed result for each item, joint or connection tested. When items are serialized, the serial numbers shall appear on the report. The reports shall contain the signature and title of an authorized Seller representative and shall accompany each shipment.

4.32 Cleaning Certification - superceded by 4.16 D.

☐ **4.33 Calibration Certification:** The Seller shall submit with each instrument/system a certification that the instrument/ system has been calibrated and is ready for use. The certification shall contain, as a minimum, the identity of the instrument/system, the identification of the calibration procedure used, identification of the standards and/or equipment utilized for the calibration, and a statement that the calibration of the standards and/or equipment used is traceable to the National Institute of Standards and Technology (NIST) or some other recognized national standard. Unless otherwise specified, detailed support data shall remain on file for minimum of three (3) years with the Seller and shall be available for review by the Buyer. The certification shall also contain the signature and title of an authorized Seller representative.

☐ **4.34 Operating-Maintenance Manual:** Documentation containing operating procedures, maintenance instructions, spare parts lists, and handling procedures shall be submitted with the shipment of the first item.

☐ **4.35 Computer Software Configuration Management:**

☐ **4.35.1** The Seller shall have and maintain an effective software configuration management system. The Seller's system shall establish requirements for placing software under configuration control, provide for the positive identification of software, and the control of all software baseline changes.

☐ **4.35.2** The Seller shall submit a copy of their software configuration management procedure(s) with their proposal for review and evaluation.

☐ **4.36 Computer Software Validation:** The Seller shall develop written procedures describing the controls applied to the design of software and the validation of the design through independent technical review. The procedures shall provide for documentation of review activities, including requirements for documenting comments and resolutions of comments. Seller software designs and review documentation shall be subject to review and approval by the Buyer.

☐ **4.37 Computer Software Verification Testing:** The Seller shall test and verify computer software developed or modified to fulfill the requirements in the procurement documentation. The verification testing shall be accomplished by a comparison of test results with those from other verified software, or by a comparison with results from analytical solutions or Buyer-approved alternatives.

☐ **4.38 Electrostatic Discharge Control:** Items that are susceptible/ sensitive to electrostatic discharge (ESDS) shall be handled and packaged to protect them from damage. Items and/or packages shall be labeled to indicate the susceptibility to electrostatic discharge.

☐ **4.39 Records:** The Seller shall retain objective evidence, including records, of the inspections and tests performed in the course of manufacturing, testing, inspecting, preserving, packaging, and preparation for shipment of procured items. These records shall be made available to the Buyer's representative for review upon request. These records shall be maintained for a minimum of three (3) years, unless otherwise specified in the procurement documentation, after the completion of the Purchase Order / contract.